

MAXIMUM STRENGTH COLD AND FLU- acetaminophen, guaifenesin, dextromethorphan hydrobromide, and phenylephrine hydrochloride capsule, liquid filled Walgreens

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

WALGREENS Maximum Strength Cold and Flu

Drug Facts

Active ingredients (in each softgel)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves common cold/flu symptoms:
- nasal congestion
- headache
- cough
- minor aches and pains
- sore throat
- sinus congestion & pressure
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 12 softgels in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy Alert

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- liver disease

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

When using this product, do not use more than directed.

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning

Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed - see Overdose warning**
- do not take more than 12 softgels in any 24 hour period
- adults & children 12 years & over : take 2 softgels every 4 hours
- children under 12 years of age: do not use

Other information

- store at 20-25 °C (68-77 °F)
- avoid excessive heat

Inactive ingredients

FD&C Yellow # 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan , titanium dioxide

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL



MAXIMUM STRENGTH COLD AND FLU

acetaminophen, guaifenesin, dextromethorphan hydrobromide, and phenylephrine hydrochloride capsule, liquid filled

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-9017	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	325 mg	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)		GUAIFENESIN	200 mg	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)		DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	5 mg	
Inactive Ingredients				
Ingredient Name			Strength	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
POVIDONE K30 (UNII: U725QWY32X)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SORBITOL (UNII: 506T60A25R)				
SORBITAN (UNII: 6O92ICV9RU)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	orange (Light orange)	Score	no score	
Shape	OVAL (OBLONG)	Size	20mm	
Flavor		Imprint Code	341;908	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9017-16	2 in 1 CARTON	08/24/2021	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		part341	08/24/2021	

Labeler - Walgreens (008965063)